COLORADO
Department of Health Care Policy & Financing

MINUTES OF THE QUARTERLY OPEN MEETING
Health First Colorado, Colorado's Medicaid Program
Drug Utilization Review Board
Department of Health Care Policy and Financing

August 9, 2022
Open Session
1:00 pm – 5:00 pm

Due to the absence of the Board's elected presiding officers for the August meeting, J Taylor asked for nominations to elect an Interim Board Chair for today's meeting. B Jackson volunteered to serve in this capacity with meeting facilitation support from J Taylor. T Brubaker moved to adopt this plan. Seconded by S Klocke. Motion passed unanimously.

1. Call to Order

Today's meeting was held virtually via Zoom. The meeting was called to order at 1:05 pm by B Jackson, Interim Board Chair.

2. Roll Call and Introductions

All board members, HCPF staff, and CO-DUR team members who were present introduced themselves. There were sufficient members for a quorum with six voting members participating. Quorum is five members.

- **Members Present:** Todd Brubaker, DO; Patricia Lanius, BSPharm, MHA; Brian Jackson, MD, MA; Shilpa Klocke, PharmD; Ingrid Pan, PharmD, Ken MacIntyre, DO
- **Members Absent:** Alison Shmerling, MD, MPH (Chair); Liza Claus, PharmD (Vice Chair)
- **HCPF Pharmacy Office Staff:** Jim Leonard, PharmD; Jeffrey Taylor, PharmD, Rachele Poissant, PharmD
- **CO-DUR Team**: Robert Page, PharmD, MSPH; Julia Rawlings, PharmD

3. Virtual Meeting Information and General Announcements

J Rawlings shared several announcements:

- This meeting is being recorded for internal use by the Department
- We ask that speakers and other attendees who are not on the Board or facilitating the meeting to remain off video with microphones muted.
- Ryan Tran and Michael Brace, University of Colorado DUR pharmacy interns, will be managing the technical aspects of today's Zoom meeting.
- Stakeholders who have signed up in advance to provide testimony will have their microphones unmuted and may turn on video at the appropriate time.
- Speakers providing testimony, and other meeting guests, are asked to keep video turned off throughout the meeting so that we can more easily see and track Board members' votes.

Reminders for Board Members:

- Video and microphone for Board members will be turned ON.

- If you experience technical difficulties or your connection interrupted during the meeting, please leave the meeting and use the same Zoom meeting link to be readmitted, as that usually resolves the issue.
- Two meeting binders containing DUR documents and written stakeholder testimony were sent to all Board members. Use the icon on the left that looks like a ribbon to quickly navigate to specific documents.
- An important reminder to all Board members to delete the meeting binders immediately following this meeting.
- Voting may be conducted by raising your hand and/or by verbal "ayes" and "nays," abstentions, and recusals as determined by the Board Chair and/or Vice-Chair.

4. Colorado Department of Health Care Policy and Financing Updates

J Taylor provided updates from the Department:

a. The Board currently has an opening for an Industry Representative. The Industry Representative serves for one year in a *non-voting* role and does not need to be a physician or pharmacist by training. Please send an email with your CV to jeffrey.taylor@state.co.us if you are interested in applying for this position.

b. For products and drug classes currently managed with DUR criteria posted on the Preferred Drug List (PDL), Appendix P (non-PDL, managed under pharmacy benefit), or Appendix Y (managed under the medical benefit) only proposed changes to currently posted criteria will be read aloud.

c. The current PDL and Appendix P are available on the Department's Pharmacy Resources page at https://hcpf.colorado.gov/pharmacy-resources. The current Appendix Y document is available at https://hcpf.colorado.gov/physician-administered-drugs.

d. Items may be moved out of Mass Review during today's meeting if a full therapeutic drug class review is needed.

e. The remaining Board meeting for 2022 is tentatively scheduled for Tuesday, November 8, from 1:00 to 5:00 pm. Board members should have already received a calendar invitation for this meeting. If you have not received an invitation, please let J Rawlings know.

5. Final Approval of Minutes from May 10, 2022 Meeting

Interim Board Chair B Jackson asked if there were any changes to propose for minutes from the May 10, 2022 DUR Board meeting. With no discussion, S Klocke moved to approve the minutes as written. Seconded by T Brubaker. Motion passed unanimously.

6. Reading of Rules for Public Testimony and Disclosure of Conflicts of Interest

J Taylor read the following rules for Board members and speakers:

Rules for Speaker Testimony: Presentations shall be restricted to products being reviewed for prior authorization criteria. Presentations shall be limited to a maximum of three minutes per drug product. Only one presentation per product will be permitted for a manufacturer. Persons must sign up no later than 24 hours in advance with the DUR Account Manager in order to speak at the DUR Board Meeting.

Persons will be called in the order in which they signed in for each set of prior authorization criteria. Presentations must be limited to verbal comments. No visual aids, other than designated handouts are permitted. Persons giving oral presentations must verbally disclose all relationships to pharmaceutical manufacturers.

DUR Board Conflicts of Interest: DUR Board Members must verbally disclose any conflicts of interest that would make it difficult to fulfill DUR Board duties in an objective manner. If a conflict of interest exists, members must recuse themselves from the applicable vote or discuss with the Board during the meeting whether the situation rises to the level of an actual conflict. If a Board member recuses, they should not participate in the discussion of the agenda item or any vote regarding that item.

7. Clinical Updates and General Orders

- **FDA New Product & Safety Updates**

  DUR Intern Mandy Li presented FDA Safety updates from June 2022. The first update concerned the withdrawal of FDA approval for Ukoniq (umbralisb) due to safety concerns. Ukoniq was originally approved to treat specific types of lymphoma. The second update concerned significant safety concerns regarding the use of Copiktra (duvelisib) to treat chronic lymphocytic leukemia (CLL) and small lymphocytic lymphoma (SLL).

  DUR Intern Johna Bezdek Thaut presented a summary of recent FDA drug approvals.

- **Quarterly Clinical Modules**

  R Page presented an update on last quarter's Quarterly Clinical Module, *Targeted Immune Modulators: Analysis of Select Biological Products*. Future module topics include an analysis of psychotropic medication use in children and adolescents and an analysis of stimulant medication use among Health First Colorado members.

- **Retrospective DUR Reports**

  R Page presented the RDUR summary.

  - Current, draft and recently retired RDUR provider letters were included in today's meeting binder. Board members may provide feedback regarding the content of these letters by sending an email to robert.page@cuanschutz.edu and julia.rawlings@state.co.us
  - Data regarding the number of members who had two or more benzodiazepine claims concomitantly for ≥ 90 days during the last two quarters is showing a steady decline.
  - The number of members who received an opioid, a benzodiazepine and a skeletal muscle relaxant concomitantly for 60 or more days (excluding individuals with a diagnosis of cancer or sickle cell disease) has shown a sharp decline from 1Q2021 to 2Q2022.
  - The number of members and providers associated with claims for opioids exceeding an average of 200 MME in a 30-day period continues an overall downward trend.
  - The number of members with multiple claims for opioid prescriptions that total >150 MME (averaged over 30 days) and no naloxone fill within the 12 months prior to, or during, the current quarter also continues to decrease over time.

- **Quarterly Drug Utilization Reports**

  Board members were referred to these reports in the meeting binder.

8. New Business

J Rawlings referred Board members to the proposed DUR criteria section of the Meeting Binder and described the steps of the review process:

- Board members will be asked if they have potential conflicts of interest to disclose prior to reviewing therapeutic drug classes or individual products listed in the meeting agenda.

- For products and drug classes being newly managed and undergoing review, all proposed criteria will be read aloud during the meeting. For products and drug classes that are currently managed with DUR criteria posted on the PDL and Appendix P, only proposed changes to the currently posted criteria will be read aloud.
- Time is permitted for stakeholder comment. All speakers have registered in advance, and each speaker will be given up to 3 minutes of time to present.
- There will be an opportunity for Board discussion.

R Page proceeded with the review process of proposed criteria.

Proposed Criteria

Red indicates proposed deleted text

Yellow indicates proposed new text

Conflict of Interest Check

No Board members reported a conflict of interest for any of the drug classes being reviewed today from the beginning of the therapeutic classes listed in the agenda up to the Mass Review section.

1. Contraceptives – Oral

Effective 01/14/22, oral contraceptive products are eligible for coverage with a written prescription by an enrolled pharmacist. Additional information regarding pharmacist enrollment can be found at https://hcpf.colorado.gov/pharm-serv.

Preferred Agents **All other rebateable oral contraceptive products are non-preferred**

Monophasic, Low:
Altavera 28 0.15-30
Apri 28 0.15-30
Aubra EQ-28 0.1-20
Aurovela FE 1-20
Aurovela FE 1.5-30
Aviane 28 0.1-20
Balziva 28 0.4-35
Blisovi FE 1-20
Blisovi FE 1.5-30
Cryselle 28 0.3-30
Cyclafem 28 1-35
Cyred 28 0.15-30
Dasetta 28 1-35
Desogestrel-Eth Estrad 28 0.15-30
Drospirenone-Eth Estrad 28 0.3-30
Drospirenone-Eth Estrad-LMF 28 3-30
Elinest 28 0.3-30
Emoquette 28 0.15-30
Enskyce 28 0.15-30
Estarylla 28 0.25-35
Ethynodiol-Eth Estrad 28 1-35
Falmina 28 0.1-20
Femynor 28 0.25-35
Hailey 21 1.5-30
Hailey FE 28 1-20
Hailey FE 28 1.5-30
Isibloom 28 0.15-30
Juleber 28 0.15-30
Junel 21 1-20
Junel 21 1.5-30
Junel FE 28 1-20
Junel FE 28 1.5-30
Kalliga 28
Kelnor 28 1-35
Kurvelo 28 0.15-30
Larin 21 1-20
Larin 21 1.5-30
Larin FE 28 1-20
Larin FE 28 1.5-30
Larissia 28 0.1-20
Lessina 28 0.1-20
Levonorgestrel-Eth Estrad 28 0.1-20
Levonorgestrel-Eth Estrad 28 0.15-30
Levora 28 0.15-30
Lillow 28 0.15-30
Low-Ogestrel 28 0.3-30
Lutera 28 0.1-20
Marlissa 28 0.15-30
Microgestin FE 28 1-20
Microgestin FE 28 1.5-30
Mili 28 0.25-35
Mono-Linyah 28 0.25-35
Necon 28 0.5-35
Norethindrone-Eth Estrad 21 1-20
Norethindrone-Eth Estrad FE 28 1-20
Norethindrone-Eth Estrad FE 28 1.5-30
Norgestimate-Eth Estrad 28 0.25-35
Nortrel 21 1-35
Nortrel 28 0.5-35
Nortrel 28 1-35
Ocella 28 3-30
Orsythia 28 1-20
Philith 28 0.4-35
Pirmella 28 1-35
Portia 28 0.15-30
Previfem 28 0.25-35
Sprintec 28 0.25-35
Sronyx 28 0.1-20
Syeda 28 3-30
Vienva 28 0.1-20
Vyfemla 28 0.4-35
Wera 28 0.5-35

Monophasic, High - Ethynodiol-Eth Estrad 28 1-50

Continuous Cycle - Levonor-Eth Estrad 28 0.9-20

Tri/Quad Phasic
Alyacen 7-7-7 28
Cyclafem 7-7-7 28
Dasetta 7-7-7 28
Enpresse 28
Levonest 28
Levonor-Eth Estrad Triphasic 28
Norgestimate-Eth Estrad 0.18-0.215-0.25/0.025
Norgestimate-Eth Estrad 0.18-0.215-0.25/0.035
Pirmella 7-7-7 28
Tri-Estarylla 28
Tri Femynor 28
Tri-Linyah 28
Tri-Lo-Estarylla 28
Tri-Lo-Marzia 28
Tri-Lo-Mili 28
Tri-Lo-Sprintec 28
Tri-Sprintec 28
Tri-Vylibra Lo 28
Velivet 7-7-7 28

Biphasic
Azurette 28
Bekyree 28
Emoquette 28
Kariva 28
Mircette 28
Pimtrea 28
Viorele 28

Progestin (norethindrone) only
Camila 28 0.35
Deblitane 28 0.35
Errin 28 0.35
Heather 28 0.35
Jencycla 28 0.35
Jolivette 28 0.35
Lyza 28 0.35
Norethindrone 28 0.35
Norlyda 28 0.35
Sharobel 28 0.35

Extended Cycle
Amethia 91 0.03 – 0.15 – 0.01
Ashlyna 91 0.15-10-30
Camrese 91
Camrese Lo 91
Drospirenone-Eth Estrad 28 3-20
Drospirenone-Eth Estrad-LMF 28 3-20
Iclevia 91 0.15-30
Jasmiel 28 3-20
Jolessa 91 0.15-30
Junel FE 24 1-20
Larin FE 24 1-20
Levonorgest-Eth Estrad 91 0.15-0.03
Levonorgest-Eth Estrad 91 0.15-0.03-0.01
Levonorgest-Eth Estrad Lo 91 0.1-0.02-0.01
Lo Loestrin FE 28 1-10
LoJaimiess 91 0.1-0.02-0.01
Loryna 28 3-20
Nikki 28 3-20
Norethindrone-Eth Estrad-FE 28 1-20 chewable
Setlakin 91 0.15-30
Tarina FE 24 1-20
Tarina FE 1-20
Tarina FE 1-20 EQ

Non-preferred oral contraceptive products may be approved if member fails one-month trial with four preferred agents OR if preferred products with medically necessary ingredients and/or doses are unavailable. Failure is defined as: allergy, intolerable side effects, or significant drug-drug interaction.

Prescriptions are eligible to be filled for up to a twelve-month supply.

Discussion
- K MacIntyre moved to accept the proposed criteria as written. Seconded by P Lanius. Motion passed unanimously.

2. Contraceptives – Topical

Topical contraceptive patch products are eligible for coverage with a written prescription by an enrolled pharmacist. Additional information regarding pharmacist enrollment can be found at https://hcpf.colorado.gov/pharm-serv.

Preferred Agents
ANNOVERA (segesterone acetate/EE) vaginal ring
NUVARING[BNR] (etonorgestrel/ethinyl estradiol) vaginal ring
XULANE (norelgestromin/ ethinyl estradiol) TD patch

Non-preferred topical contraceptive products may be approved following a trial and failure of one preferred topical contraceptive product. Failure is defined as lack of efficacy, allergy, intolerable side effects, or significant drug-drug interaction.

PHEXXI (lactic acid/citric acid/potassium) vaginal gel may be approved for members who meet the following criteria:

- Medication is being prescribed for the prevention of pregnancy **AND**
- Member is unable to use any of the following methods of contraception due to failure, contraindication, intolerance, or preference:
    - Injection (such as medroxyprogesterone acetate)
    - Oral Contraceptive
    - Transdermal Patch
    - Vaginal Contraceptive Ring
    - Diaphragm
    - Cervical Cap

  AND
- PHEXXI (lactic acid/citric acid/potassium) is not being prescribed concomitantly with a vaginal ring product, **AND**
- Provider attests that member has been counseled regarding a higher rate of pregnancy prevention with the use of other methods of contraception (such as injection, oral contraception, transdermal patch, vaginal ring) as compared to PHEXXI.

Prescriptions are eligible to be filled for up to a twelve-month supply.

Note: Depot and IUD formulations are billed through the medical benefit.

Discussion

- S Klocke moved to accept the proposed criteria as written. Seconded by T Brubaker. Motion passed unanimously.

3. Diabetes Management Class, Insulins

a. Rapid-Acting Insulins

Preferred Agents

HUMALOG (insulin lispro) 100 U/mL cartridge, vial, KwikPen, pen
HUMALOG Jr. (insulin lispro) KwikPen
Insulin aspart cartridge, pen, vial
Insulin lispro pen, vial
Insulin lispro, Jr. Kwikpen
NOVOLOG (insulin aspart) cartridge, vial, FlexTouch pen

Non-preferred products may be approved following trial and failure of treatment with two preferred products (failure is defined as allergy [hives, maculopapular rash, erythema multiforme, pustular rash, severe hypotension, bronchospasm, and angioedema] or intolerable side effects).

Afrezza (human insulin) may be approved if meeting the following criteria:

- Member is 18 years or older AND
- Member has trialed and failed treatment with two preferred products (failure is defined as allergy [hives, maculopapular rash, erythema multiforme, pustular rash, severe hypotension, bronchospasm, or angioedema] or intolerable side effects) AND
- Member must not have chronic lung disease such as COPD or asthma AND
- If member has type 1 diabetes, must use in conjunction with long-acting insulin AND

- Member must not be a smoker Prescriber acknowledges that Afrezza is not recommended in patients who smoke or have recently stopped smoking.

Discussion
- A question was raised about the rationale for the proposed edit for Afrezza. J Rawlings provided information that the new language more closely reflects current product labeling.
- T Brubaker moved to accept the proposed criteria as written. Seconded by I Pan. Motion passed unanimously.

b. Long-Acting Insulins

Preferred Agents

LANTUS (insulin glargine) vial, Solostar
LEVEMIR (insulin detemir) vial, FlexTouch

Non-preferred products may be approved if the member has failed treatment with Levemir AND Lantus (failure is defined as allergy or intolerable side effects).

Scheduled testimony presentations:

J Chardoulias, Treseba – Novo Nordisk

Discussion
- A question was asked about the inclusion of biosimilars in this insulin sub-class. J Taylor explained that determination of preferred products is conducted by the P&T Committee and the Department based on safety, efficacy, cost and other factors.
- K MacIntyre moved to accept the proposed criteria as written. Seconded by S Klocke. Motion passed unanimously.

c. Insulin Mixtures

Preferred Agents

HUMALOG MIX 50/50 Kwikpen, vial
HUMALOG MIX 75/25 Kwikpen, vial
HUMULIN 70/30 (OTC) Kwikpen, vial
Insulin aspart protamine/insulin aspart 70/30 FlexPen, vial (generic Novolog Mix)
Insulin lispro protamine/insulin lispro 75/25 Kwikpen (generic Humalog Mix)
NOVOLOG MIX 70/30 FlexPen

Non-preferred products may be approved if the member has failed treatment with two of the preferred products (failure is defined as: allergy or intolerable side effects).

Discussion
- T Brubaker moved to accept the proposed criteria as written. Seconded by S Klocke. Motion passed unanimously.

4. Diabetes Management Class, Non-Insulin

a. GLP-1 Analogues

Preferred Agents

***Must meet eligibility criteria**

*BYETTA (exenatide)
*TRULICITY (dulaglutide)
*VICTOZA (liraglutide)

*Preferred products may be approved for members with a diagnosis of type 2 diabetes following a 3-month trial of (or documented contraindication to) metformin prior to initiation of therapy.

Non-preferred products may be approved for members with a diagnosis of type 2 diabetes following trial and failure of a 3-month trial of metformin **AND** a 3-month trial of two preferred products. Failure is defined as lack of efficacy (such as not meeting hemoglobin A1C goal despite adherence to regimen), allergy, intolerable side effects, limited dexterity resulting in the inability to administer doses of a preferred product, or a significant drug-drug interaction.

Maximum Dose:
Prior authorization is required for all products exceeding maximum dose listed in product package labeling.

Table 1: GLP-1 Analogue Maximum Dose	
Adlyxin (lixisenatide)	20 mcg per day
Bydureon BCISE (exenatide)	2 mg weekly
Byetta (exenatide)	20 mcg per day
Mounjaro (tirzepatide)	15 mg weekly
Ozempic (semaglutide)	1 mg weekly
Rybelsus (semaglutide)	14 mg daily
Trulicity (dulaglutide)	4.5 mg weekly
Victoza (liraglutide)	1.8 mg per day

Note: Authorization for GLP-1 analogues prescribed solely for weight loss will not be approved.

Scheduled testimony presentations:
J Chardoulias, Ozempic – Novo Nordisk
J Chardoulias, Rybelsus – Novo Nordisk

Discussion
- S Klocke moved to increase the maximum dose for Ozempic (semaglutide) to 2 mg weekly in Table 1, based on recent FDA approval of the higher dose. Seconded by I Pan. Motion passed unanimously.
- S Klocke moved to accept the proposed criteria as amended. Seconded by I Pan. Motion passed unanimously.

b. Sodium-Glucose Cotransporter 2 inhibitors (SGLT-2is)

Preferred Agents
FARXIGA (dapagliflozin)
INVOKANA (canagliflozin)
JARDIANCE (empagliflozin)

Non-preferred products may receive approval following trial and failure with two preferred products. Failure is defined as lack of efficacy with 3-month trial (such as not meeting hemoglobin A1C goal despite adherence to regimen), allergy, intolerable side effects, or a significant drug-drug interaction.

FARXIGA (dapagliflozin), INVOKANA (canagliflozin) and JARDIANCE (empagliflozin) are contraindicated in members on dialysis.

STEGLATRO (ertugliflozin) therapy is not recommended in patients when with an eGFR is persistently 30 to less than 60 <45 mL/min/1.73 m^2 and it is contraindicated in patients with an eGFR less than 30 mL/min/1.73 m^2 or on dialysis.

Maximum Dose:
Prior authorization is required for all products exceeding maximum dose listed in product package labeling.

Discussion
- A question was raised about provision of eGFR results for the purpose of prior authorization (PA). J Taylor explained that, administratively, providers need only provide a yes/no acknowledgement of the renal function screening questions during the PA process.
- S Klocke moved to accept the proposed criteria as written. Seconded by K MacIntyre. Motion passed unanimously.

5. Glucagon, Self-administered

Preferred Agents
***Must meet eligibility criteria**
*BAQSIMI (glucagon) nasal powder
GLUCAGEN HYPOKIT (glucagon)
Glucagon Emergency Kit *(Lilly only)*
GVOKE (glucagon)* Hypopen, Syringe
*ZEGALOGUE (dasiglucagon) autoinjector

*Gvoke (glucagon BAQSIMI (glucagon) or ZEGALOGUE (dasiglucagon) autoinjector may be approved following trial and failure of GlucaGen (glucagon) OR athe preferred glucagon emergency kit (failure is defined as allergy to ingredients in product, intolerable side effects, or inability to administer dosage form).

Non-preferred products may be approved if the member has failed treatment with BAQSIMI (glucagon) or ZEGALOGUE (dasiglucagon) autoinjector Gvoke (glucagon) AND one other preferred product (failure is defined as allergy to ingredients in product, intolerable side effects, or contraindication to dosing form).

Quantity limit for Seconded-line preferred (Gvoke) and non-preferred products: 2 doses per year unless used / damaged / lost

Scheduled testimony presentations:
D Bondugji, Gvoke - Xeris Pharmaceuticals

Discussion
- A question was raised about the Department's process for monitoring drug shortages. J Taylor and J Leonard explained that shortage monitoring is conducted by Magellan Rx, the State's pharmacy benefit manager (PBM), and information about drug shortages is communicated on a regular basis to the Department.
- B Jackson moved to edit failure definitions for 2nd line and non-preferred agents to include both inability to administer dosage form and contraindication to dosing form so they will match. Seconded by I Pan. Motion passed unanimously.
- T Brubaker moved to accept the proposed criteria as amended. Seconded by S Klocke. Motion passed unanimously.

6. Growth Hormones

Preferred Agents
No PA Required (if diagnosis and dose met)
GENOTROPIN (somatropin) cartridge, Miniquick pen
NORDITROPIN (somatropin) Flexpro pen

All preferred products may be approved if the member has one of the qualifying diagnoses listed below (diagnosis may be verified through AutoPA) AND if prescription does not exceed limitations for maximum dosing (Table 1).

Non-preferred Growth Hormone products may be approved if the following criteria are met:

- Member failed treatment with one preferred growth hormone product (failure is defined as lack of efficacy, allergy, intolerable side effects or significant drug-drug interactions).
- Member has a qualifying diagnosis:
  - Prader-Willi Syndrome (PWS)
  - Chronic renal insufficiency/failure requiring transplantation (defined as Creatinine Clearance < 30 mL/min)
  - Turner's Syndrome
- Hypopituitarism: as a result of pituitary disease, hypothalamic disease, surgery, radiation therapy or trauma verified by one of the following:
  - Has failed at least one GH stimulation test (peak GH level < 10 ng/mL)
  - Has at least one documented low IGF-1 level (below normal range for patient's age – refer to range on submitted lab document)
  - Has deficiencies in ≥ 3 pituitary axes (i.e.such as TSH, LH, FSH, ACTH, ADH)
  - Cachexia associated with AIDS
  - Noonan Syndrome
  - Short bowel syndrome
  - Neonatal symptomatic growth hormone deficiency (limited to 3-month PA approval)
- Prescription does not exceed limitations for FDA-labeled maximum dosing for prescribed indication based on prescriber submission/verification of patient weight from most recent clinical documentation

Table 1: Growth Hormone Product Maximum Dosing*

Medication	Pediatric Maximum Dosing (age < 18 years)	Adult Maximum Dosing (age ≥ 18 years)
Genotropin	0.33 mg/kg/week	0.08 mg/kg/week
Humatrope	0. 47375 mg/kg/week	0.0875 mg/kg/week
Norditropin Flexpro	0.47 mg/kg/week	0.112 mg/kg/week
Nutropin AQ Nuspin	0.3757 mg/kg/week	0.175 mg/kg/week for ≤35 years of age 0.0875 mg/kg/week for >35 years of age
Omnitrope	0.4833 mg/kg/week	0.08 mg/kg/week
Saizen	0.18 mg/kg/week	0.07 mg/kg/week
Serostim	Not Indicated	42 mg/week for cachexia with HIV only (in combination with antiretroviral therapy)
Skytrofa	0.24 mg/kg/week	0.24 mg/kg/week
Zomacton	0.47375 mg/kg/week	0.0875 mg/kg/week
Zorbtive	Not Indicated	8 mg/28 days for short bowel syndrome only

*Based on FDA labeled indications and dosing

Scheduled testimony presentations:

T Maravilla, Skytrofa – Ascendis Pharma

Discussion

- S Klocke moved to accept the proposed criteria as written. Seconded by P Lanius. Motion passed unanimously.

Mass review drug classes*

**Proposed criteria for drug classes designated for mass review will not be read aloud at the time of DUR Board review, as there are no proposed changes to criteria currently implemented for these designated classes. The DUR Board may determine if designated mass review drug classes will undergo full review based on board vote.*

Conflict of Interest Check

No Board members reported a conflict of interest for any drug classes or products being reviewed today within the Mass Review section.

7. Bone Resorption Suppression and Related Agents

a. Bisphosphonates

Preferred Agents
Alendronate tablet, solution
Ibandronate tablet

Non-preferred bisphosphonates may be approved for members who have failed treatment with one preferred product at treatment dose. Failure is defined as lack of efficacy with a 12-month trial, allergy, intolerable side effects, or significant drug-drug interaction.

For members who have a low risk of fracture, discontinuation of bisphosphonate therapy and drug holiday should be considered following 5 years of treatment. Low risk is defined as having a bone mineral density, based on the most recent T-score, of greater than (better than) -2.5 AND no history of low trauma or fragility fracture.

b. Non-Bisphosphonates

Preferred Agents
NONE

CALCITONIN SALMON (nasal) may be approved if the member meets the following criteria:

- Member has a diagnosis of post-menopausal osteoporosis (BMD T-scores of -2.5 or less) **AND**
- Has trial and failure of preferred bisphosphonate for 12 months (failure is defined as: lack of efficacy, allergy, intolerable side effects, or significant drug-drug interaction) **OR**
- Member cannot swallow solid oral dosage forms or has a feeding tube.

Quantity limit: One spray daily

RALOXIFENE may be approved if the member meets the following criteria:

- Diagnosis of postmenopausal osteoporosis (BMD T-scores of -2.5 or less) AND
- Has trial and failure of preferred bisphosphonate for one year (Failure is defined as: lack of efficacy, allergy, intolerable side effects, or significant drug-drug interaction)

Maximum dose: 60 mg daily

FORTEO (teriparatide) or **generic teriparatide** may be approved if the member meets the following criteria:

- Member has one of the following diagnoses:
  - Osteoporosis, (BMD T-scores of -2.5 or less) primary or hypogonadal in men
  - Osteoporosis due to corticosteroid use
  - Postmenopausal osteoporosis

  AND
- Member is post-menopausal with very high risk for fracture* **OR** member has history of trial and failure of a preferred bisphosphonate for one year. Failure is defined as lack of efficacy, allergy, intolerable side effects, or significant drug-drug interaction **AND**
- For brand FORTEO, member has trialed and failed generic teriparatide. Failure is defined as lack of efficacy, allergy, intolerable side effects, or significant drug-drug interaction **AND**
- Prior authorization will be given for one year and total exposure of parathyroid hormone analogs (Forteo and Tymlos) shall not exceed two years

Maximum dose: 20 mcg daily

TYMLOS (abaloparatide) may be approved if the member meets the following criteria:

- Member has a diagnosis of postmenopausal osteoporosis (BMD T-scores of -2.5 or less) **AND**
- Member is post-menopausal with very high risk for fracture* **OR** member has history of trial and failure of a preferred bisphosphonate for one year (Failure is defined as: lack of efficacy, allergy, intolerable side effects, or significant drug-drug interaction) **AND**
- Prior authorization will be given for one year and total exposure of parathyroid hormone analogs (Forteo and Tymlos) shall not exceed two years.

Maximum dose: 80 mcg daily

All other non-preferred non-bisphosphonates may be approved for members who have failed treatment with one preferred bisphosphonate product at treatment dose. Failure is defined as lack of efficacy with a 12-month trial, allergy, unable to use oral therapy, intolerable side effects, or significant drug-drug interaction.

*Members at very high risk for fracture: Members will be considered at very high risk for fracture if they meet one of the following:

- A history of fracture within the past 12 months **OR**
- Fractures experienced while receiving guideline-supported osteoporosis therapy **OR**
- A history of multiple fractures **OR**
- A history of fractures experienced while receiving medications that cause skeletal harm (such as long-term glucocorticoids) **OR**
- A very low T-score (less than -3.0) **OR**
- A high risk for falls or a history of injurious falls **OR**
- A very high fracture probability by FRAX (> 30% for a major osteoporosis fracture or > 4.5% for hip fracture)

Note: Prior authorization criteria for Prolia (denosumab) and other injectable bone resorption and related agents are listed on Appendix P.

8. Diabetes Management Class, Insulins

a. Short-acting

Preferred Agents
HUMULIN R U-100 (insulin regular) vial (OTC)
HUMULIN R U-500 (insulin regular) concentrated vial, Kwikpen
NOVOLIN R U-100 (insulin regular) FlexPen (OTC)

Non-preferred products may be approved following trial and failure of treatment with one preferred product (failure is defined as allergy or intolerable side effects).

b. Intermediate-acting

Preferred Agents
HUMULIN N U-100 (insulin NPH) vial (OTC)
NOVOLIN N U-100 (insulin NPH) FlexPen (OTC)

Non-preferred products may be approved following trial and failure of treatment with one preferred product (failure is defined as allergy or intolerable side effects).

9. Diabetes Management Class, Non-insulins

a. Amylin

Preferred Agents
NONE

SYMLIN (pramlintide) may be approved following trial and failure of metformin AND trial and failure of a DPP4-inhibitor or GLP-1 analogue. Failure is defined as lack of efficacy (such as not meeting hemoglobin A1C goal despite adherence to regimen) following 3-month trial, allergy, intolerable side effects, or a significant drug-drug interaction. Prior authorization may be approved for Symlin (pramlintide) products for members with a diagnosis of Type 1 diabetes without requiring trial and failure of other products.

Maximum Dose: Prior authorization will be required for doses exceeding FDA-approved dosing listed in product package labeling.

b. Biguanides

Preferred Agents
Metformin 500 mg, 850 mg, 1,000 mg tablets
Metformin ER 500 mg, 750 mg tablets (generic Glucophage XR)

Non-preferred products may be approved for members who have failed treatment with two preferred products. Failure is defined as lack of efficacy, allergy, intolerable side effects, or significant drug-drug interaction.

Liquid metformin may be approved for members who meet one of the following:

- Member is under the age of 12 with a feeding tube **OR**
- Prescriber confirms that member has difficulty swallowing

c. DPP-4 Inhibitors

Preferred Agents

***Must meet eligibility criteria**

*JANUVIA (sitagliptin) tablet
*TRADJENTA (linagliptin) tablet

*Approval for preferred products require a 3-month trial of (or documented contraindication to) metformin prior to initiation of therapy.

Non-preferred DPP-4 inhibitors may be approved after a member has failed a 3-month trial of metformin AND a 3-month trial of two preferred products. Failure is defined as lack of efficacy (such as not meeting hemoglobin A1C goal despite adherence to regimen), allergy, intolerable side effects, or a significant drug-drug interaction.

Maximum Dose:

Prior authorization will be required for doses exceeding the FDA-approved maximum dosing listed in the following table:

DPP-4 Inhibitor	FDA-Approved Maximum Dose
Alogliptin (generic Nesina)	25 mg/day
Januvia (sitagliptin)	100 mg/day
Nesina (alogliptin)	25 mg/day
Onglyza (saxagliptin)	5 mg/day
Tradjenta (linagliptin)	5 mg/day

d. Meglitinides

Preferred Agents

NONE

Non-preferred products may be approved for members who have failed treatment with one sulfonylurea. Failure is defined as: lack of efficacy (such as not meeting hemoglobin A1C goal despite adherence to regimen), allergy, intolerable side effects, or significant drug-drug interaction.

e. Thiazolidinediones (TZDs)

Preferred Agents

Pioglitazone

Non-preferred agents may be approved following trail and failure of metformin AND trial and failure of one preferred product. Failure is defined as lack of efficacy (such as not meeting hemoglobin A1C goal despite adherence to regimen) with a 3-month trial, allergy, intolerable side effects, or a significant drug-drug interaction.

f. Combinations

1. DPP-4 Inhibitors – Combination with Metformin

Preferred Agents

***Must meet eligibility criteria**

*JANUMET (sitagliptin/metformin)
*JANUMET XR (sitagliptin/metformin)
*JENTADUETO (linagliptin/metformin)
*JENTADUETO XR (linagliptin ER/metformin ER)

*Approval for preferred combination agent products require a 3-month trial of (or documented contraindication to) metformin prior to initiation of therapy.

Non-preferred combination products may be approved for members who have been stable on the two individual ingredients of the requested combination for three months **AND** have had adequate three-month trial and failure of a preferred combination agent. Failure is defined as lack of efficacy (such as not meeting hemoglobin A1C goal despite adherence to regimen), allergy, intolerable side effects, or a significant drug-drug interaction.

2. SGLT-2 Inhibitor Combinations with Metformin

Preferred Agents

INVOKAMET (canagliflozin/metformin)
INVOKAMET XR (canagliflozin/metformin)
XIGDUO XR (dapagliflozin/metformin)

Non-preferred products may be approved for members who have been stable on the two individual ingredients of the requested combination for 3 months.

INVOKAMET, INVOKAMET XR, SYNJARDY, SYNJARDY XR and XIGDUO XR are contraindicated in patients with an eGFR less than 30 mL/min/1.73 m^2 or on dialysis. SEGLUROMET therapy is not recommended when eGFR is persistently 30 to less than 60 45 mL/min/1.73 m^2 and it is contraindicated in patients with an eGFR less than 30 mL/min/1.73 m^2 or on dialysis.

3. Meglitinides Combination with Metformin

Preferred Agents

NONE

Non-preferred products may be approved for members who have been stable on the two individual ingredients of the requested combination for 3 months.

10. Phosphate Binders

Preferred Agents

Calcium acetate capsule
PHOSLYRA (calcium acetate) solution
RENAGEL (sevelamer HCl) 800 mg tablet
RENVELA[BNR] (sevelamer carbonate) tablet, powder pack
Sevelamer HCl 800 mg tablet

Prior authorization for non-preferred products in this class may be approved if member meets all the following criteria:

- Member has diagnosis of end stage renal disease AND
- Member has elevated serum phosphorus [> 4.5 mg/dL or > 1.46 mmol/L] AND
- Provider attests to member avoidance of high phosphate containing foods from diet AND
- Member has trialed and failed‡ one preferred agent (lanthanum products require trial and failure‡ of a preferred sevelamer product).

Auryxia (ferric citrate) may be approved if the member meets all the following criteria:

- Member is diagnosed with end-stage renal disease, receiving dialysis, and has elevated serum phosphate (> 4.5 mg/dL or > 1.46 mmol/L) AND
- Provider attests to counseling member regarding avoiding high phosphate containing foods from diet AND
- Member has trialed and failed‡ three preferred agents with different mechanisms of action prescribed for hyperphosphatemia in end stage renal disease
  OR
- Member is diagnosed with chronic kidney disease with iron deficiency anemia and is not receiving dialysis AND
- Member has tried and failed‡ at least two different iron supplement product formulations (OTC or RX)

Velphoro (sucroferric oxyhydroxide tablet, chewable) may be approved if the member meets all of the following criteria:

- Member is diagnosed with chronic kidney disease and receiving dialysis and has elevated serum phosphate (> 4.5 mg/dL or > 1.46 mmol/L) AND
- Provider attests to counseling member regarding avoiding high phosphate containing foods from diet AND
- Member has trialed and failed‡ two preferred agents, one of which must be a preferred sevelamer product

Maximum Dose: Velphoro 3,000 mg daily

Members currently stabilized on a non-preferred lanthanum product may receive approval to continue therapy with that product.

‡Failure is defined as lack of efficacy with 6 week trial, allergy, intolerable side effects, or significant drug-drug interaction.

Note: Medications administered in a dialysis unit or clinic are billed through the Health First Colorado medical benefit or Medicare with members with dual eligibility.

11. Prenatal Vitamins/Minerals

Preferred Agents

***Must meet eligibility criteria**

COMPLETE NATAL DHA tablet
M-NATAL PLUS tablet
NESTABS tablets
PNV 29-1 tablet
Prenatal Vitamin Plus Low Iron tablet
PREPLUS CA-FE 27 mg – FA 1 mg tablet

SE-NATAL 19 chewable tablet
Taron-C DHA Capsule
THRIVITE RX tablet
TRINATAL RX 1 tablet
VITAFOL gummies
VP-PNV-DHA softgel
WESTAB PLUS tablet

All other rebateable prescription products are non-preferred

*****Preferred and non-preferred prenatal vitamin products are a benefit for members from 11-60 years of age who are pregnant, lactating, or trying to become pregnant.

Prior authorization for non-preferred agents may be approved if member fails 7-day trial with four preferred agents. Failure is defined as: allergy, intolerable side effects, or significant drug-drug interaction.

12. Antihyperuricemics

Preferred Agents
Allopurinol tablet
Colchicine tablet
Probenecid tablet
Probenecid/Colchicine tablet

Non-preferred xanthine oxidase inhibitor products (allopurinol or febuxostat formulations) may be approved following trial and failure of preferred allopurinol. Failure is defined as lack of efficacy, allergy, intolerable side effects, or significant drug-drug interaction. If member has tested positive for the HLA-B*58:01 allele, it is not recommended that they trial allopurinol. A positive result on this genetic test will count as a failure of allopurinol.

Prior authorization for all other non-preferred agents (non-xanthine oxidase inhibitors) may be approved after trial and failure of two preferred products. Failure is defined as lack of efficacy, allergy, intolerable side effects, or significant drug-drug interaction.

GLOPERBA (colchicine) oral solution may be approved for members who require individual doses <0.6 mg OR for members who have documented swallowing difficulty due to young age and/or a medical condition (preventing use of solid oral dosage form).

Colchicine tablet quantity limits:
- Chronic hyperuricemia/gout prophylaxis: 60 tablets per 30 days
- Familial Mediterranean Fever: 120 tablets per 30 days

13. Benign Prostatic Hyperplasia (BPH) Agents

Preferred Agents
Alfuzosin ER tablet
Doxazosin tablet
Dutasteride capsule
Finasteride tablet
Tamsulosin capsule
Terazosin capsule

Prior authorization for non-preferred products in this class may be approved if member meets all of the following criteria:

- Member has tried and failed‡ three preferred agents AND
- For combinations agents, member has tried and failed‡ each of the individual agents within the combination agent and one other preferred agent.

‡Failure is defined as lack of efficacy with 8-week trial, allergy, intolerable side effects, contraindication to, or significant drug-drug interaction.

***CIALIS (tadalafil)** may be approved for members with a documented diagnosis of BPH who have failed a trial of finasteride (at least 3 months in duration) AND either a trial of a nonselective alpha blocker (therapeutic dose for at least two months) OR a trial of tamsulosin (therapeutic dose for at least one month).

Documentation of BPH diagnosis will require BOTH of the following:

- AUA Prostate Symptom Score ≥ 8 AND
- Results of a digital rectal exam.

Cialis (tadalafil) will not be approved for any patient continuing alpha-blocker therapy, as this combination is contraindicated in this population.

Doses exceeding 5mg per day of Cialis (tadalafil) will not be approved.

14. Overactive Bladder Agents

Preferred Agents
GELNIQUE (oxybutynin) gel packets
MYRBETRIQ (mirabegron) tablet
Oxybutynin IR, ER tablets, syrup
Oxybutynin ER tablets
Solifenacin tablet
TOVIAZ[BNR] (fesoterodine ER)

Non-preferred products may be approved for members who have failed treatment with two preferred products. Failure is defined as: lack of efficacy, allergy, intolerable side effects, or significant drug-drug interaction.
Members with hepatic failure can receive approval for trospium (Sanctura) or trospium extended release (Sanctura XR) products without a trial on a Preferred product.

Discussion

- K MacIntyre moved to pull Estrogen Agents out of today's Mass Review for further discussion. Seconded by S Klocke. Motion passed unanimously.
- I Pan moved to pull Androgenic Agents out of today's Mass Review for further discussion. Seconded by S Klocke. Motion passed unanimously.
- S Klocke moved to accept the proposed criteria in Mass Review, except for Androgen and Estrogen Agents, as written. Seconded by L MacIntyre. Motion passed unanimously.

15. Androgenic Agents, Topical, Injectable, Oral

Preferred Agents
PA Required for all agents in this class
ANDRODERM (testosterone) patch
ANDROGEL[BNR] (testosterone) gel 1.62% pump
Testosterone cypionate IM injection vial
Testosterone 1% 5g gel packet *(Upsher Smith only)*

Injectable testosterone cypionate is a pharmacy benefit when self-administered. Administration in an office setting is a medical benefit.

Hypogonadotropic or Primary Hypogonadism (may be Secondary to Klinefelter Syndrome):

Preferred products may be approved for members meeting the following:
- Member is a male patient > 16 years of age with a documented diagnosis of hypogonadotropic or primary hypogonadism OR ≥ 12 years of age with a diagnosis of hypogonadotropic or primary hypogonadism Secondary to Klinefelter Syndrome (all other diagnoses will require manual review) AND
- Member has two documented low serum testosterone levels below the lower limit of normal range for testing laboratory prior to initiation of therapy AND
- Member does not have a diagnosis of breast or prostate cancer AND
- If the member is > 40 years of age, has prostate-specific antigen (PSA) < 4 ng/mL or has no palpable prostate nodule AND
- Member has baseline hematocrit < 50%

Reauthorization Criteria (requests for renewal of a currently expiring prior authorization for a preferred product may be approved for members meeting the following criteria):

- Member is a male patient > 16 years of age with a documented diagnosis of hypogonadotropic or primary hypogonadism OR ≥ 12 years of age with a diagnosis of hypogonadotropic or primary hypogonadism secondary to Klinefelter Syndrome AND
- Serum testosterone is being regularly monitored (at least annually) to achieve total testosterone level in the middle tertile of the normal reference range AND
- Member does not have a diagnosis of breast or prostate cancer AND
- Member has a hematocrit < 54%

Gender Transition/Affirming Hormone Therapy:

Preferred androgenic drugs may be approved for members meeting the following:
1. Female sex assigned at birth > 16 years of age AND
2. Is undergoing female to male transition AND
3. Has a negative pregnancy test prior to initiation AND
4. Has baseline hematocrit < 50% or hematocrit < 54% for continuation of therapy.

Non-Preferred Products:
Non-preferred **topical** androgenic agents may be approved for patients meeting the above criteria with trial and failed‡ therapy with two preferred topical androgen formulations.

Non-preferred **injectable** androgenic agents may be approved for patients meeting the above criteria with trial and failed‡ therapy with a preferred injectable androgenic drug.

Prior authorization for **oral** androgen agents (tablet, capsule, buccal) may be approved if member has trialed and failed‡ therapy with a preferred topical agent AND testosterone cypionate injection.

‡Failure is defined as lack of efficacy with 8 week trial, allergy, intolerable side effects, contraindication to, or significant drug-drug interaction.

For all agents and diagnoses, members < 16 years of age will require a manual prior authorization review by a pharmacist (with exception of members ≥ 12 years of age with a diagnosis of hypogonadotropic or primary hypogonadism secondary to Klinefelter Syndrome).

Discussion

- A point was raised that hypogonadism due to various causes is observed in members younger than ages 12 or 16 years. J Taylor offered that a prior authorization (PA) expanded review process is in place to clinically evaluate individual cases that fall outside the scope of the current DUR criteria.
- B Jackson moved to add this language to the first bullets of both authorization and reauthorization criteria "OR at any age in conjunction with an endocrinologist." Seconded by T Brubaker. Motion passed unanimously.
- The Board discussed a general concern that a healthcare professional who has a moral or religious objection could be involved in reviewing, and possibly denying, PA requests for gender transition/affirming cases. J Taylor explained that the State has a PA exception and formal appeals process in place and no evidence of reviewer bias of this type has yet been identified.
- K MacIntyre moved to request that the Department follow up with the PA vendor to ensure there is a process in place to handle personal or religious objection situations should they arise for PA review involving any therapeutic drug class, then report the findings back to the Board during the November 2022 meeting. Seconded by I Pan. T Brubaker abstained. Motion passed, with five members voting in favor.
- S Klocke moved to accept the proposed criteria for Androgenic Agents as amended. Seconded by K MacIntyre. Motion passed unanimously.

16. Estrogen Agents – Oral, Transdermal, Injectable/parenteral

Preferred Agents

Oral/Transdermal

CLIMARA[BNR] (estradiol) patch
Estradiol oral tablet
MINIVELLE[BNR] (estradiol) patch
VIVELLE-DOT[BNR] (estradiol) patch

Parenteral

DELESTROGEN[BNR] (estradiol valerate) vial
DEPO-ESTRADIOL (estradiol cypionate) vial

Non-preferred **parenteral** estrogen agents may be approved with trial and failure of one preferred parenteral agent. Failure is defined as lack of efficacy, allergy, intolerable side effects, or significant drug-drug interaction.

Non-preferred **oral** estrogen agents may be approved with trial and failure of one preferred oral agent. Failure is defined as lack of efficacy, allergy, intolerable side effects, or significant drug-drug interaction.

Non-preferred **transdermal** estrogen agents may be approved with trial and failure of two preferred agents. Failure is defined as lack of efficacy, allergy, intolerable side effects, or significant drug-drug interaction.

Table 1: Transdermal Estrogen FDA-Labeled Dosing	
ALORA (estradiol) patch	2/week
CLIMARA (estradiol) patch	1/week
DOTTI (estradiol) patch	2/week
Estradiol patch (once weekly)	1/week
Estradiol patch (twice weekly)	2/week
LYLLANA (estradiol) patch	2/week
MENOSTAR (estradiol) patch	1/week
MINIVELLE (estradiol) patch	2/week
VIVELLE-DOT (estradiol) patch	2/week

Note: Estrogen agents are a covered benefit for gender transition/affirming hormone therapy.

Discussion

- S Klocke moved to add the word "transdermal" to the third non-preferred agent paragraph so that it reads "Non-preferred transdermal estrogen agents may be approved with trial and failure of two preferred transdermal agents." Seconded by T Brubaker. Motion passed unanimously.
- The Board discussed the potential need for more specific safety-related criteria for gender transition/affirming therapy within the estrogen class. J Taylor offered that androgens are controlled substances with a higher propensity for abuse, which has most likely resulted in the existence of more detailed criteria to drive appropriate utilization in that class.
- S Klocke moved to
    1) request that the Department to create more specific criteria for estrogen agents being used for gender affirming and gender transition therapy
    2) request that the Department follow up with the PA vendor to ensure there is a process in place to handle personal or religious objection situations should they arise (similar to the previous motion for the Estrogen Agents)
    3) accept the criteria for Androgenic Agents as amended.

  Seconded by K MacIntyre. Motion passed unanimously.

9. Proposed Prior Authorization Criteria for Non-PDL Products Managed Under the Pharmacy Benefit

Conflict of Interest Check

No Board members reported a conflict of interest for any of the three drug products being reviewed today in this section.

1. **PYRUKYND (mitapivat)** tablet

Pyrukynd (mitapivat) may be approved if the following criteria are met:

1. Member is ≥ 18 years of age **AND**
2. PYRUKIND (mitapivat) is being used for treatment of hemolytic anemia with pyruvate kinase deficiency with least 2 variant alleles in the pyruvate kinase liver and red blood cell (PKLR) gene, of which at least 1 is a missense variant **AND**
3. Member does not have moderate to severe hepatic impairment, **AND**
4. Due to the risk of developing acute hemolysis, provider confirms that member has been counseled to avoid abrupt discontinuation of PYRUKIND (mitapivat) therapy **AND**
5. Prescriber confirms that potentially significant drug-drug interactions (such as those with itraconazole, ketoconazole, fluconazole, rifampin, efavirenz and other CYP3A inhibitors and inducers) will be carefully evaluated prior to initiating therapy with PYRUKIND (mitapivat), based on the current product labeling

Maximum Dose: 100 mg/day

Quantity Limit: 2 tablets/day

Initial authorization: 6 months

Reauthorization: Reauthorization may be approved for 12 months if prescriber attests to observed benefit after 24 weeks of Pyrukynd (mitapivat) therapy, based on hemoglobin and hemolysis laboratory results and transfusion requirements.

Scheduled testimony presentations:
D Bartos, Pyrukind – Agios Pharmaceutics

Discussion
- B Jackson moved to 1) change reauthorization language to "based on hemoglobin and/or hemolysis laboratory results and/or transfusion requirements." Seconded by S Klocke. Motion passed unanimously.
- P Lanius moved to accept the proposed criteria as amended. Seconded by K MacIntyre. Motion passed unanimously.

2. **VIJOICE (alpelisib)** tablet

VIJOICE (alpelisib) may be approved if the following criteria are met:

1. Member is ≥ 2 years of age **AND**
2. Member requires systemic therapy for severe manifestations of PIK3CA-Related Overgrowth Spectrum (PROS) **AND**
3. Due to the risk of severe adverse reactions, provider confirms that VIJOICE (alpelisib) will not be used in the oncology setting **AND**
4. Prescriber confirms that potentially significant drug-drug interactions with strong CYP3A4 inducers (such rifampin, carbamazepine, phenytoin and St. John's Wort) will be carefully evaluated prior to initiating therapy with VIJOICE (alpelisib), based on the current product labeling **AND**
5. Prescriber attests that a pre-treatment pregnancy test will be performed for members of reproductive potential and that member will be advised to use effective contraception (including condoms for male patients) during treatment and for 1 week after the final dose **AND**

6. Provider and patient or caregiver are aware that continued US FDA approval of VIJOICE (alpelisib) for PIK3CA-Related Overgrowth Spectrum may be contingent upon verification and description of clinical benefit in confirmatory trial(s).

Maximum Dose: 250 mg/day

Scheduled testimony presentations:

J Hardisty, Vijoice – Novartis – *Speaker yielded time*

Discussion

- T Brubaker moved to accept the proposed criteria as written. Seconded by P Lanius. Motion passed unanimously.

3. CAMZYOS (mavacamten) capsule

CAMZYOS (mavacamten) may be approved if the following criteria are met:

1. Member is ≥ 18 years of age **AND**
2. Member is able to swallow capsules **AND**
3. Member is being treated for symptomatic New York Heart Association (NYHA) class II-III obstructive hypertrophic cardiomyopathy AND has a left ventricular ejection fraction of ≥ 55% **AND**
4. CAMZYOS is being prescribed by, or in consultation with, a cardiologist **AND**
5. Echocardiogram assessment of LVEF has been performed prior to initiation of CAMZYOS therapy and will be repeated periodically during treatment **AND**
6. Member has tried and failed **ALL** of the following, up to maximally indicated doses. (Failure is defined as contraindication, lack of efficacy, allergy, intolerable side effects, or significant drug-drug interaction):
   a. Non-vasodilating beta blocker (any beta blocker except carvedilol or nebivolol)
   b. Non-dihydropyridine calcium channel blocker (such as verapamil, diltiazem)
   c. Disopyramide

   AND
7. Due to increased risk of systolic heart failure, member's medication profile has been reviewed for potential drug interactions with CYP2C19 or CYP3A4 inhibitors (such as fluoxetine, omeprazole, esomeprazole, cimetidine, itraconazole, ketoconazole, fluconazole, ritonavir, diltiazem, verapamil) according to product labeling **AND**
8. Member does not have severe hepatic impairment (Child-Pugh C) **AND**
9. Members of reproductive potential have been counseled to use effective contraception during treatment with CAMZYOS (mavacamten) and for 4 months after the last dose.

Maximum Dose: 25 mg/day (unless on certain interacting medications)

Quantity Limit: 30 capsules/30 days

Initial authorization: 180 days

Reauthorization: Approval for CAMZYOS may be reauthorized for 1 year if LVEF > 50% and member's clinical status is stable or improved.

Scheduled testimony presentations:

K Bayo, Camzyos – Bristol Myers Squibb

Discussion

- DUR intern H. Ryan Tran read aloud the proposed DUR criteria for Camzyos.
- S Klocke moved to accept the proposed criteria as written. Seconded by K MacIntyre. Motion passed unanimously.

---

10. Proposed Prior Authorization Criteria for Non-PDL Physician Administered Drug Products Managed Under the Pharmacy Benefit and Medical Benefit

(J-Codes listed for medical benefit management)

1. J3241 Tepezza (teprotumumab)

Tepezza may be approved if the member meets the following criteria:

1. For claims billed through the pharmacy benefit, prescriber verifies that the medication is being administered by a healthcare professional in the member's home or in a long term care facility AND
2. Member is 18 years of age or older AND
3. Member has a diagnosis of Graves' disease **AND** moderate to severe Thyroid Eye Disease (TED), with onset of TED symptoms within the previous 9 months, AND includes at least ONE of the following
    a. Lid retraction ≥ 2 mm
    b. Moderate or severe soft tissue involvement
    c. Proptosis ≥ 3 mm above normal
    d. Periodic or constant diplopia

    AND
4. Member has documentation of baseline thyroid eye disease clinical activity score ≥ 4 AND
5. Member's prescriber must be or in consultation with an ophthalmologist or endocrinologist AND
6. Member does not require immediate surgical ophthalmological intervention AND
7. Member does not currently require orbital (eye) surgery and is not planning corrective surgery/irradiation during therapy AND
8. Member is euthyroid, mild hypothyroid, mild hyperthyroid (defined as free thyroxine (FT4) and free triiodothyronine (FT3) levels less than 50% above or below the normal limits) or seeking care for dysthyroid state from an endocrinologist or other provider experienced in the treatment of thyroid diseases AND
9. Member does not have corneal decompensation unresponsive to medical management AND
10. Member had an inadequate response, or there is a contraindication or intolerance, to high-dose intravenous glucocorticoids AND
11. Member is not pregnant AND
12. If member is diabetic, member is being managed by an endocrinologist or other provider experienced in the treatment and stabilization of diabetes AND
13. Authorization will be issued for one course of therapy of eight infusions

Scheduled testimony presentations:

B Hurtgen, Tepezza – Horizon Therapeutics

Discussion

- K MacIntyre moved to add language to bullet point 11 to expand pregnancy safety criteria. Proposed language "avoid pregnancy with effective contraception before starting therapy, during therapy and for 6 months after stopping therapy." Seconded by P Lanius. Motion passed unanimously.

- K MacIntyre moved to accept criteria as amended. Seconded by P Lanius. Motion passed unanimously.

2. J1303 Ultomiris (ravulizumab)

J1303 **Ultomiris (ravulizumab-cwvz)** may be approved if member meets the following criteria:

1. Medication is being administered in the member's home or in a long-term care
2. facility by a healthcare professional AND
3. Member has a diagnosis of either

1. For claims billed through the pharmacy benefit, prescriber verifies that the medication is being administered by a healthcare professional in the member's home or in a long term care facility AND
2. Member is diagnosed with either Paroxysmal Nocturnal Hemoglobinuria (PNH), Atypical Hemolytic Uremic Syndrome (aHUS), or Generalized Myasthenia Gravis (gMG) AND
3. Member has been vaccinated for meningococcal disease according to current ACIP guidelines at least two weeks prior to Ultomiris initiation OR
4. Member is receiving 2 weeks of antibacterial drug prophylaxis if meningococcal vaccination cannot be administered at least 2 weeks prior to starting Ultomiris AND
5. Member does not have unresolved *Neisseria meningitidis* or any systemic infection
6. Prescriber is enrolled in the Ultomiris Risk Evaluation and Mitigation Strategy (REMS) program AND
7. Medication is administered by or in consultation with a hematologist for PNH and by or in consultation with a hematologist or nephrologist for aHUS and by or in consultation with a neurologist for gMG NAD
8. Member meets criteria listed below for specific diagnosis:
    a. Pparoxysmal nocturnal hemoglobinuria (PNH)
        i. Member is one month of age or older if prescribing the IV formulation OR is ≥ 18 years of age if prescribing the subcutaneous formulation AND
        ii. Diagnosis of PNH must be accompanied by detection of PNH clones by flow cytometry diagnostic testing AND
        iii. Baseline values are documented for the following:
            1. Serum lactate dehydrogenase (LDH)
            2. Hemoglobin levels
            3. Packed RBC transfusion requirement
        iv. AND
        v. Member has one of the following indications for therapy:
            1. Presence of a thrombotic event
            2. Presence of organ dysfunction Secondedary to chronic hemolysis
            3. Member is transfusion dependent
            4. Member has uncontrolled pain Secondedary to chronic hemolysis
    b. OR Aatypical hemolytic uremic syndrome (aHUS).
        i. Member is one month of age or older if prescribing the IV formulation OR is ≥ 18 years of age if prescribing the subcutaneous formulation AND
        ii. Member does not have Shiga toxin E. coli related HUS (STEC-HUS) AND

iii. Thrombotic Thrombocytopenic Purpura (TTP) has been ruled out by evaluating ADAMTS13 level or a trial of plasma exchange did not result in clinical improvement AND
iv. Baseline values are documented for the following:
1. Serum LDH
2. Serum creatinine/eGFR
3. Platelet count
4. Dialysis requirement

c. Generalized myasthenia gravis
i. Member is 18 years of age or older AND
ii. Member has a positive serologic test for anti-acetylcholine receptor (AchR) antibodies
iii. Member has Myasthenia Gravis Foundation of America (MGFA) Clinical Classification of Class II to IV disease; AND
iv. Member has a MG-Activities of Daily Living (MG-ADL) total score of ≥6; AND
v. Member has trial and failure of treatment over at least 1 year with at least 2 immunosuppressive therapies (e.g., azathioprine, cyclosporine, mycophenolate, etc.), or has failed at least 1 immunosuppressive therapy and required chronic plasmapheresis or plasma exchange (PE) or intravenous immunoglobulin (IVIG)

Maximum dose: Ultomiris 3.6 g every 8 weeks (IV infusion) or 490 mg once weekly (subcutaneous administration)

Discussion

- S Klocke moved 1) to request correction of 'AND' typo in bullet point 7, and 2) to accept the proposed criteria as amended. Seconded by T Brubaker. Motion passed unanimously.

3. J2796 Nplate (romiplostim)

J2796 **Nplate (romiplostim)** may be approved if the member meets the following criteria:

1. For claims billed through the pharmacy benefit, prescriber verifies that the medication is being administered by a healthcare professional in the member's home or in a long term care facility AND
2. Member does not have thrombocytopenia due to myelodysplastic syndrome (MDS) or any cause of thrombocytopenia other than immune thrombocytopenia AND
3. Nplate is not being used in an attempt to normalize platelet counts AND
4. If being administered for hematopoietic subsyndrome of acute radiation syndrome, member has been acutely exposed to myelosuppressive radiation levels greater than 2 gray (Gy)
OR
5. If being administered for immune thrombocytopenia (ITP)
a. Member has had an insufficient response to corticosteroids, immunoglobulins, or splenectomy AND
b. Member has ITP whose degree of thrombocytopenia and clinical condition increases the risk for bleeding as indicated by a platelet count of ≤ 30,000/mm^3 AND
c. Laboratory value for platelet count is current (e.g., drawn within the previous 28 days) AND
d. If being administered for Acute ITP
i. Member is at least 18 years of age or older
OR
e. If being administered for Chronic ITP

i. Member is at least 1 years of age or older AND
ii. Member has had chronic ITP for at least 6 months
AND

6. Maximum weekly dose of 10 mcg/kg

Reauthorization may be approved for ITP if member met the initial indication-specific approval criteria above and member responded to treatment by achieving and maintaining a platelet count of ≥ 50,000/mm^3, but <450,000/mm^3

Scheduled testimony presentations:

C Johnson, Nplate – Amgen *Speaker yielded time*

Discussion

- S Klocke moved to accept the proposed criteria as written. Seconded by K MacIntyre. Motion passed unanimously.

4. J3032 Vyepti (eptinezumab)

J3032 **Vyepti (eptinezumab-jjmr)** may be approved if member meets the following criteria:

1. For claims billed through the pharmacy benefit, prescriber verifies that the medication is being administered by a healthcare professional in the member's home or in a long term care facility AND
2. Member is 18 years of age or older AND
3. Member has a diagnosis of episodic or chronic migraine, which is defined as headaches occurring 15 days or more monthly, where at least 8 of these days per month for at least 3 months are migraine days with or without aura
AND
4. Member has tried and failed two oral preventive pharmacological agents listed as Level A per the most current American Headache Society/American Academy of Neurology guidelines (such as divalproex, topiramate, metoprolol, propranolol). Failure is defined as lack of efficacy, allergy, intolerable side effects, or significant drug-drug interaction AND
5. The requested medication is not being used in combination with another CGRP medication
AND
6. Member has trial and failure of all preferred calcitonin gene-related peptide inhibitors (CGRPis) indicated for preventative therapy listed on the pharmacy benefit preferred drug list
AND
7. Initial dose is no more than 100 mg every 3 months
    a. If Vyepti 300 mg is requested, the member has tried and had an inadequate response to the 100 mg dosage.
8. Initial authorization will be limited to 6 months. Continuation (12-month authorization) will require documentation of clinically relevant improvement with no less than 30% reduction in headache frequency in a 4-week period.

Maximum dose: 300 mg IV every 3 months

Discussion

- B Jackson moved to add language to bullet point 7.a to further define an inadequate response. Proposed language "clinically relevant improvement with no less than 30% reduction in headache frequency" same as in bullet point 8. Seconded by P Lanius. Motion passed unanimously.

- S Klocke moved to add language to bullet point 3 to add a definition of episodic migraine. Seconded by P Lanius. Motion passed unanimously.
- P Lanius moved to accept the criteria as amended. Seconded by I Pan. Motion passed unanimously.

5. Select Agents Used for Lupus:

a. J0490 Benlysta (belimumab)

Benlysta (belimumab) may be approved if the following criteria are met:

1. For claims billed through the pharmacy benefit, prescriber verifies that the medication is being administered by a healthcare professional in the member's home or in a long term care facility AND
2. Member is age ≥ 5 years with active, autoantibody-positive systemic lupus erythematosus (SLE) and receiving standard therapy OR member is an adult with active lupus nephritis who are receiving standard therapy AND
3. Member has incomplete response to standard therapy from at least two of the following therapeutic classes: antimalarials, immunosuppressants and glucocorticoids; AND
4. Member maintains standard therapy while on Benlysta (belimumab) AND
5. Member is not receiving other biologics or intravenous cyclophosphamide AND
6. The product is NOT being prescribed for severe active lupus nephritis or severe active central nervous system lupus

Maximum dosage of 10 mg/kg at 2-week intervals for the first 3 doses and 4-week intervals thereafter

Discussion

- I Pan moved to 1) add indication for lupus nephritis in members ≥ 5 years of age based on recent FDA approval, and 2) accept the proposed criteria as amended. Seconded by K MacIntyre. Motion passed unanimously.

b. J0491 Saphnelo (anifrolumab)

J0491 **Saphnelo (anifrolumab)** may be approved if member meets the following criteria:

1. For claims billed through the pharmacy benefit, prescriber verifies that the medication is being administered by a healthcare professional in the member's home or in a long term care facility AND
2. Member is ≥ 18 years of age with active, autoantibody-positive, moderate to severe systemic lupus erythematosus (SLE) AND is currently receiving standard therapy AND
3. The product is NOT being prescribed for severe active lupus nephritis or severe active central nervous system lupus AND
4. Member has had incomplete response to standard therapy from at least two of the following therapeutic classes: antimalarials, immunosuppressants and glucocorticoids AND
5. Member will maintain standard therapy for SLE while receiving Saphnelo (anifrolumab) therapy

Maximum Dose: 300 mg IV every 4 weeks

Quantity Limit: One 300 mg vial/28 days

Scheduled testimony presentations:

S Hirpara, Saphnelo – AstraZeneca

Discussion

- B Jackson moved to 1) require providers to attest that members are informed about the unknown effects of ocrelizumab during pregnancy, 2) require that providers inform members who are pregnant or become pregnant during therapy about the Saphnelo pregnancy registry and encourage them to participate. Seconded by K MacIntyre. S Klocke abstained. Motion passed, with five members voting in favor.
- K MacIntyre moved to accept the criteria as amended. Seconded by P Lanius. S Klocke abstained. Motion passed, with five members voting in favor.

6. Select Agents Used for Pompe Disease:

a. J0221 Lumizyme (alglucosidase alfa)

J0221 **Lumizyme (alglucosidase alfa)** may be approved if member meets the following criteria:

1. For claims billed through the pharmacy benefit, prescriber verifies that the medication is being administered by a healthcare professional in the member's home or in a long term care facility AND
2. Member has a differential and definitive diagnosis of Pompe disease confirmed by one of the following:
    a. Deficiency of acid alpha-glucosidase (GAA) enzyme activity OR
    b. Detection of biallelic pathogenic variants in the GAA by molecular genetic testing

    AND
3. If being administered for infantile-onset Pompe disease
    a. Member has documented baseline age appropriate motor function tests, muscle weakness, respiratory function, cardiac involvement testing, percent predicted forced vital capacity (FVC), and 6-minute walk test (6MWT)

    OR
4. If being administered for Late-onset Pompe disease
    a. Member has documented baseline age appropriate motor function tests, muscle weakness, respiratory function, cardiac involvement testing, FVC and 6MWT

Reauthorization may be approved if member met initial approval criteria at the time of initiation of therapy AND

1. For infantile-onset disease: the member has shown clinical improvement defined as an improvement or stabilization in muscle weakness, motor function, respiratory function, cardiac involvement, percent predicted FVC, and/or 6MWT
    OR
2. For late-onset disease: the member has shown clinical improvement defined as an improvement or stabilization in percent predicted FVC and/or 6MWT
    AND
3. Member is being monitored for antibody formation and hypersensitivity

Maximum dosage of 20 mg/kg administered every 2 weeks

b. J0219 Nexviazyme (avalglucosidase)

J0219 **Nexviazyme (avalglucosidase alfa-ngpt)** may be approved if member meets the following criteria:

1. For claims billed through the pharmacy benefit, prescriber verifies that the medication is being administered by a healthcare professional in the member's home or in a long term care facility AND
2. Member is 1 year of age or older AND
3. Member has a diagnosis of late-onset (non-infantile) Pompe disease AND

4. Member has a differential and definitive diagnosis of Pompe disease confirmed by one of the following:
    a. Deficiency of acid alpha-glucosidase (GAA) enzyme activity OR
    b. Detection of biallelic pathogenic variants in the GAA by molecular genetic testing

AND

5. Nexviazyme is not being used in combination with other enzyme replacement therapies AND
6. Member has documented baseline age appropriate motor function tests, muscle weakness, respiratory function, cardiac involvement testing, percent predicted FVC and 6MWT
7. Product is being prescribed by a provider specializing in the treatment of Pompe disease AND
8. Prescriber will consider administering antihistamines, antipyretics, and/or corticosteroids prior to Nexviazyme (avalglucosidase alpha) administration to reduce the risk of severe infusion-associated reactions.

Reauthorization may be approved if member met initial approval criteria at the time of initiation of therapy AND

1. Member has shown clinical improvement defined as an improvement or stabilization in percent predicted FVC and/or 6MWT
2. Member is being monitored for antibody formation and hypersensitivity

Maximum weight dependent dosage:
Members ≥30 kg, 20 mg/kg administered every 2 weeks
Members ≤30 kg, 40 mg/kg administered every 2 weeks

Discussion

- Proposed criteria for Lumizyme (alglucosidase alfa) and Nexviazyme (avalglucosidase) were presented back-to-back.
- B Jackson moved to 1) revisit Boolean operators (AND, OR) in the first part of Lumizyme criteria to make them less confusing and easier to follow, 2) delete the words 'differential and' from Lumizyme bullet point 4. Seconded by S Klocke. Motion passed unanimously.
- K MacIntyre moved to accept the criteria for Lumizyme and Nexviazyme as amended. Seconded by T Brubaker. Motion passed unanimously.

7. Select Agents Used for Multiple Sclerosis

a. J2350 Ocrevus (ocrelizumab)

J2350 **Ocrevus (ocrelizumab)** may be approved for initial therapy if member meets the following criteria:

1. For claims billed through the pharmacy benefit, prescriber verifies that the medication is being administered by a healthcare professional in the member's home or in a long term care facility AND
2. <u>If administered for Relapsing Forms of Multiple Sclerosis (MS)</u>
    a. Member is 18 years of age or older AND
    b. Member has a relapsing form of multiple sclerosis AND
    c. Member has experienced one relapse within the prior year or two relapses within the prior two years AND
    d. Member has trial and failure of three two of the following: Tysabri (natalizumab), Lemtrada (alemtuzumab), or the preferred agents in the "Disease Modifying Therapies" PDL drug class that are FDA-labelled for use for the same prescribed indication." Failure will be defined as intolerable side effects, drug-drug interaction, or lack of efficacy. Lack of efficacy will be defined as one of the following:
        i. One of the following on MRI: presence of any new spinal lesions, cerebellar or brainstem lesions, or change in brain atrophy

ii. On clinical exam, signs and symptoms consistent with functional limitations that last one month or longer

OR

e. Member with highly active relapsing MS has trial and failure of one of the following: Tysabri (natalizumab), Lemtrada (alemtuzumab), or a preferred agent in the "Disease Modifying Therapies" PDL drug class that are FDA-labelled for use for the same prescribed indication.

OR

3. If administered for Primary Progressive Multiple Sclerosis
   a. Member is 18 years of age or older AND
   b. Member is not concomitantly taking disease modifying therapies.

AND

4. Member does not have active hepatitis B infection AND
5. Ocrevus is administered by or in consultation with a neurologist or a physician that specializes in the treatment of multiple sclerosis AND
6. Maximum maintenance dose: 600 mg every 6 months

Exemption: If member is currently receiving and stabilized on Ocrevus, they may continue to receive prior authorization approval to continue

f. J2323 Tysabri (natalizumab)

J2323 **Tysabri (natalizumab)** may be approved for initial therapy if the following criteria are met:

1. For claims billed through the pharmacy benefit, prescriber verifies that the medication is being administered by a healthcare professional in the member's home or in a long term care facility AND
2. Medication is not currently being used in combination with immunosuppressants (azathioprine, 6-mercaptopurine, methotrexate) or TNF-alpha inhibitors (adalimumab, certolizumab pegol, infliximab) AND
3. If administered for induction of remission of moderate to severe Crohn's disease
   a. The member is ≥ 18 years of age AND
   b. Member has tried and failed Aminosalicylates AND
   c. Member has tried and failed Corticosteroids AND
   d. Member has tried and failed immunomodulators AND
   e. Member has tried and failed two TNF-alpha inhibitors (e.g. adalimumab, • certolizumab pegol, infliximab) AND
   f. Tysabri is administered by or in consultation with a gastroenterologist.
4. If administered for relapsing remitting multiple sclerosis (RRMS)
   a. The member is ≥ 18 years of age; AND
   b. Member has trial and failure of three two of the following: Ocrevus (ocrelizumab), Lemtrada (alemtuzumab), or the preferred agents in the "Disease Modifying Therapies" PDL drug class that are FDA-labelled for use for the same prescribed indication. Failure will be defined as intolerable side effects, drug-drug interaction, or lack of efficacy indicated by one of the following:
      i. One of the following on MRI: presence of any new spinal lesions, cerebellar or brainstem lesions, or change in brain atrophy
      ii. On clinical exam, signs and symptoms consistent with functional limitations that last one month or longer OR
   c. Member with highly active relapsing MS has trial and failure of one of the following: Ocrevus (ocrelizumab), Lemtrada (alemtuzumab), or a preferred agent in the "Disease Modifying Therapies" PDL drug class that are FDA-labelled for use for the same prescribed indication.
      i. AND
   d. Tysabri is administered by or in consultation with a neurologist or a physician that specializes in the treatment of multiple sclerosis

5. Exemption: If member is currently receiving and stabilized on Tysabri, they may continue to receive prior authorization approval to continue.

8. J0202 Lemtrada (alemtuzumab)

J0202 **Lemtrada (alemtuzumab)** may be approved if member meets the following criteria:

1. For claims billed through the pharmacy benefit, prescriber verifies that the medication is being administered by a healthcare professional in the member's home or in a long term care facility AND
2. Member is 18 years of age or older AND
3. Member has a relapsing form of multiple sclerosis AND
4. Member has experienced one relapse within the prior year or two relapses within the prior two years AND
5. Member has trial and failure of Tysabri (natalizumab), Ocrevus (ocrelizumab), or two preferred agents in the "Disease Modifying Therapies" PDL drug class that are FDA-labelled for use for the same prescribed indication." Failure will be defined as intolerable side effects, drug-drug interaction, or lack of efficacy. Lack of efficacy will be defined as one of the following:
    a. One of the following on MRI: presence of any new spinal lesions, cerebellar or brainstem lesions, or change in brain atrophy
    b. On clinical exam, signs and symptoms consistent with functional limitations that last one month or longer
6. AND
7. Lemtrada is administered by or in consultation with a neurologist or a physician that specializes in the treatment of multiple sclerosis AND
8. Baseline skin exam and thyroid function assessment are completed and documented prior to initiation of treatment with Lemtrada AND
9. Prescriber is enrolled in the Lemtrada Risk Evaluation and Mitigation Strategy (REMS) program
10. Exemption: If member is currently receiving and stabilized on Lemtrada, they may continue to receive prior authorization approval to continue.

Stakeholder input:

Written testimony, S Schaefer, NP – UCHealth Neurology and MS Comprehensive Care Center

Scheduled testimony presentations:

A Declusin, Dept of Neurology MS Group, CU Anschutz Medical Campus
T Sova, Tysabri – Biogen *Speaker yielded time*
M Puyear, Ocrevus - Genentech

Discussion

- Ocrevus, Tysabri and Lemtrada were reviewed as one section.
- The Board discussed that, based on current clinical practice, an anti-CD20 agent (such as Ocrevus (ocrelizumab, Kesimpta (ofatumumab) or Tysabri (natalizumab) should be considered for highly active disease. A recommendation was also made that safety screenings included for individual agents should be listed near the top of PA criteria for these agents.
- S Klocke moved that the Department consider these revisions within the Agents for Multiple Sclerosis (MS) section:
    1. Consider re-evaluating trial and failure criteria (or removing trial and failure requirements) for cases of highly active MS disease
    2. Consider listing some of the specific characteristics of highly active MS disease
    3. Add to Ocrevus criteria "member has been screened for hypogammaglobulinemia at baseline"
    4. Add to Ocrevus and Tysabri criteria "member does not have anti-JC virus antibodies at baseline"

5. Simplify Ocrevus bullet point 4.e to "Member has highly active relapsing MS"
6. Simplify Tysabri (natalizumab) bullet point 4.c to "Member has highly active relapsing MS"
7. To increase access to Ocrevus and Tysabri for relapsing multiple sclerosis, consider trial and failure of just one other agent rather than two other agents
8. Consider adding "trial and failure and/or contraindication" phrase to criteria for Ocrevus and Tysabri
9. Consider adding consultation with a psychiatrist regarding members with known psychiatric conditions who are pre-treating with high dose oral corticosteroids prior to starting Lemtrada (alemtuzumab) therapy.

Seconded by K MacIntyre. Motion passed unanimously.

---

11. Proposed Prior Authorization Criteria for Non-PDL Physician Administered Drug Products Managed Under the Medical Benefit

- **J0178 Eylea (aflibercept)**

J0178 **Eylea (afibercept)** may be approved if member meets the following criteria:

1. Member is 18 years of age or older AND
2. Member has a definitive diagnosis of one of the following and dosing is appropriate for the specified diagnosis as follows:
    a. Neovascular (Wet) Age-Related Macular Degeneration
        i. Maximum dose of 2 mg (0.05 mL) administered every 4 weeks for the first 12 weeks, followed by 2 mg (0.05 mL) every 8 weeks thereafter
    b. Diabetic macular edema
        i. Maximum dose of 2 mg (0.05 mL) administered every 8 weeks
    c. Macular edema following retinal vein occlusion
        i. Maximum dose of 2 mg (0.05 mL) administered every 4 weeks
    d. Diabetic retinopathy
        i. Maximum dose of 2 mg (0.05 mL) administered every 8 weeks

    AND
3. Eylea (afibercept) is prescribed by or in consultation with an ophthalmologist AND
4. Eylea (afibercept) is not being used in combination with any other anti-vascular endothelial growth factor (VEGF) medication AND
5. Member does not have any of the following:
    a. Ocular or periocular infection
    b. Active intraocular inflammation
    c. Hypersensitivity to Eylea

Reauthorization criteria: Reauthorization may be approved if member met initial approval criteria at the time of initiation of therapy AND the provider attests that the member has shown clinical improvement defined as an improvement or stabilization in visual acuity

Discussion

- T Brubaker moved to accept the criteria as written. Seconded by K MacIntyre. Motion passed unanimously.

12. Adjournment

J Rawlings reminded attendees that the next Board meeting is scheduled for Tuesday, November 8, from 1:00 to 5:00 pm on Zoom, and also reminded Board members to delete their meeting binders at the conclusion of today's meeting.

K MacIntyre moved to adjourn the meeting, Seconded by I Pan. Motion passed unanimously. The meeting was adjourned at 5:00 pm.

Minutes respectfully submitted by Julia Rawlings, PharmD